amendments to the claims herein, claims 1, 7, 28, 38 and 40 have been amended. Claims 48-59 have been canceled. No new matter has been added by the amendments herein, full support for the amendments being found throughout the originally-filed specification, claims and drawings.

The Invention

The invention is directed to the problem of how to accurately anchor a catheter within a passageway in a mammalian body wherein the catheter allows the measuring of certain characteristics of the patient's bodily functions at a specific location within the passageway. As explained in the application, the problem frequently arises where it is desired to position a sensing device at a specific location within a blood vessel to measure various characteristics of blood flowing at a particular location within the blood vessel. It is also explained in the application that the problem also arises where the catheter is adapted to locate a translumenal ultrasonic sensor to obtain images of blood vessels.

The invention solves this problem by providing a unique anchoring system comprising an inner lumen disposed within an outer lumen. In all of the embodiments of the invention, the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end. As explained in the application on page 11, this bore allows sensing devices to be inserted through the inner lumen to the desired site within the passageway.

Rejections Under 35 U.S.C. § 112

The examiner has rejected claims 1, 2, 7-11, 22 and 24-59 under 35 U.S.C. § 112, second paragraph, as being indefinite. It is the examiner's position that the term "deployment means" in claims 1, 28, 38 and 48 are vague and ambiguous.

By the amendments herein, claim 48 has been canceled and all references to "deployment means" in the remaining claims have been changed to "deployment element." Accordingly, applicants respectfully requests that the rejections under 35 U.S.C. § 112 be withdrawn.

Rejections Under 35 U.S.C. § 102

The examiner has rejected claims 1, 2, 11 and 22 under 35 U.S.C. § 102(b) as being anticipated by Cathcart et al. (U.S. Pat. No. 5,681,347). The examiner has also rejected claims 1, 2, 7, 10, 11, 22, 48-50 and 53-55 under 35 U.S.C. § 102(b) as being anticipated by Goldberg et al. (U.S. Pat. No. 5,152,777). Finally, the examiner has rejected claims 38-40, 44 and 45 under 35 U.S.C. § 102(e) as being anticipated by Hayashi (U.S. Pat. No. 5,910,144). Applicants respectfully traverse these rejections.

The Cathcart et al. Reference

Applicants respectfully submit that the rejections of claims 1, 2, 11 and 22 as being anticipated by Cathcart et al.

are in error. Each of claims 1, 2, 11, 22 are limited to devices having an inner lumen "with a bore extending completely through the inner lumen from the proximal end to the distal end." The device taught by Cathcart et al., however, does not disclose or fairly suggest the use of an inner lumen having such a bore.

As noted in applicant's Preliminary Amendment, Cathcart et al. discloses a vena cava filter delivery system as follows (emphasis added):

> A delivery system 10...comprises a proximal base 11 suited for positioning exteriorly of a patient and a distal portion 12 for insertion into a patient. The distal portion 12 includes an outer tubular member 12 proximally extending along an axis 14 from a distal end 15 of the system 10 to a handle 16 of the proximal base 11, **an inner member 17** co-axially underlying the outer member 13 and extending distally from the handle 16, and a metal tubular segment 20. The metal segment 20 has a substantially smooth inner bore.

Referring to Fig. 3, a **cup shaped portion 21** engages a proximal end 22 of a device 23, such as a vena cava filter having radially extending penetrating or hook portions 24 disposed within the inner portion of the metal segment 20.... Displacement of the inner member 17 distally relative to the outer member 13

moves the cup shaped portion 21 from the first position depicted in FIG. 3 through a second position depicted in FIG. 4 to a third position depicted in FIG. 5 in which the cup shaped portion 21 distally extends beyond the distal end 15 and the filter 23 deploys in a patient's lumen. [col. 5, line 47 through col. 6. line 2]

Claim 1 in the present application, by contrast, contains the limitation that the apparatus for anchoring a tubular element comprises:

> ...a deployment element positioned within the outer lumen and slidable with respect to the outer lumen, the deployment means comprising a hollow tubular inner lumen with a wall having an inner surface, where the inner lumen has a proximal end and a distal end, and **where the inner lumen has a bore extending completely through the inner lumen from the proximal end to the distal end**...

As can be appreciated from these passages among others, and from the figures, the inner member 17 is not described as a "deployment element" in Cathcart et al. In fact, the deployment element in Cathcart et al. necessarily includes the cup shaped portion 21 sealing the distal end of the inner member 17 to deploy the device 23 as disclosed in Cathcart et al. Otherwise, the deployment element disclosed in Cathcart et al. will not

work. By contrast, the deployment element as claimed in claim 1 has a bore extending completely through the inner lumen from the proximal end to the distal end. Therefore, claim 1 as presently written is neither anticipated nor even suggested by Cathcart et al., as Cathcart et al. does not disclose a deployment element with "a bore extending completely through the inner lumen from the proximal end to the distal end."

Additionally, claim 1 contains the limitation "...each anchoring member being **reversibly movable** by the deployment element between a first position and a second position..." (emphasis added). The 'anchoring member' (the filter 23) disclosed in Cathcart et al. does not appear to be 'reversibly movable by the deployment element (delivery system 10) between a first position and a second position.' Indeed, the disclosure in Cathcart et al. appears to be limited to non-reversible deployment of the filter 23 by the delivery system 10. For example:

> ..Thus, once the metal segment 20 and the stop 33 engage, the continued relate proximal displacement of the outer tubular member 13 relative to the filter 23 caused the deployment of the filer 23 from the distal end 15 with the cup shaped member 21 moving through the metal segment 20 to the position depicted in FIG.5. After deployment of the filter 23, the delivery system 10 is

withdrawn by retracting the outer tubular member 13 either along the guidewire, if it remains so positioned, or merely along the path defined by the outer tubular member 13. [col. 7, lines 4-15]

As previously requested in the Preliminary Amendment, if the Patent and Trademark Office continues to take the position that Cathcart et al. anticipates claim 1, the Patent and Trademark Office is requested to specifically identify the disclosure in Cathcart et al. that anticipates the limitation "...each anchoring member being reversibly movable by the deployment element between a first position and a second position..." present in claim 1.

For each of the reasons given above, claim 1 is believed to be patentable over Cathcart et al. Claims 2, 10-11 and 22 depend on claim 1. Therefore, withdrawal of the rejection under 35 U.S.C. §102(b) is hereby requested.

The Goldberg et al. Reference

Applicants also respectfully submit that the rejection of claims 1, 2, 7, 10, 11, 22, 48-50 and 53-55 as being anticipated by Goldberg et al. should be withdrawn. Like the device taught by Cathcart et al., the device taught by Goldberg et al. does not disclose or fairly suggest the use of an inner lumen having a bore extending completely through the inner lumen

from the proximal end to the distal end as required by claims 1, 2, 7, 10, 11 and 22. Claims 48-50 and 53-55 have been canceled.

Like the Cathcart et al. reference, the Goldberg et al. reference discloses a vena cava filter delivery system. Like Cathcart et al., there is nothing in Goldberg et al. which addresses the problem of how to anchor a sensing device at a specific location within a passageway of a mammalian patient. Accordingly, it is not surprising that Goldberg et al. does not teach or fairly suggest an anchoring system using an inner lumen having a bore extending completely through the inner lumen from the proximal end to the distal end. In Goldberg et al., the innermost passageway is blocked at the junction of elements 94 and 96 as illustrated in Figure 5A. Accordingly, Goldberg et al. does not anticipate claims 1, 2, 7, 10, 11 and 22 as alleged. Thus, the rejection of those claims under 35 U.S.C. § 102 should be withdrawn.

The Hayashi Reference

Applicants also respectfully submit that the rejection of claims 28-40, 44 and 45 as being anticipated by Hayashi should be withdrawn. Like the devices taught by Cathcart et al. and Goldberg et al., the device taught by Hayashi does not disclose or fairly suggest the use of an inner lumen having a bore extending completely through the inner lumen from the proximal end to the distal end as required in claims 28-40, 44 and 45.

The Hayashi reference teaches a prosthesis gripping system for enabling the manipulation of a prosthesis deployed or implanted at a repair site. As is the case with the Cathcart et al. and the Goldberg et al. references, the Hayashi reference is not directed to the problem of how to locate a sensor at a specific location within the passageway of a mammalian patient. Thus, it is again not surprising that the Hayashi reference fails to teach the use of an inner lumen having a bore which extends from its proximal end to its distal end.

The closest thing to any form of an inner lumen disclosed in the Hayashi reference is an element termed "tube 50" which is described in column 4 as being an alternative method for securing the elements 40 to the distal end of the wire 36. However, it is clear from the text in column 4 between lines 23 and 37 that the tube 50 does not define a bore which extends "completely through the [tube 50] from the proximal end to the distal end." As can be from the text in column 4, the tube 50 is crimped to form the joint between the wire 36 and the secured ends 42 of elements 40. Such crimping necessarily closes off the proximal end of the tube 50. Accordingly, the device taught in the Hayashi reference does <u>not</u> anticipate claims 28-40, 44 and 45. The rejection of those claims as being anticipated by Hayashi under 35 U.S.C. § 102 should be withdrawn.

<u>Rejections Under 35 U.S.C. § 103</u>

The examiner has rejected claims 8-10 under 35 U.S.C. § 103(a) as being unpatentable over Cathcart et al. in view of

Hayman et al. (U.S. Pat. No. 5,267,960) and Abrams (U.S. Pat. No. 5,492,119). The examiner has also rejected claims 8, 9, 26, 51, 52 and 58 under 35 U.S.C. § 103(a) as being unpatentable over Goldberg et al. in view of Abrams. The examiner has also rejected claims 27 and 59 under 35 U.S.C. § 103(a) as being unpatentable over Goldberg et al. in view of Lefebvre (U.S. Pat. No. 5,938,683). The examiner has also rejected claims 24, 25, 28-30, 33-36, 56 and 57 under 35 U.S.C. § 103(a) as being unpatentable over Goldberg et al. in view of Hayashi. The examiner has also rejected claims 31 and 32 under 35 U.S.C. § 103(a) as being unpatentable over Goldberg et al. in view of Hayashi and Abrams. The examiner has also rejected claim 37 under 35 U.S.C. § 103(a) as being unpatentable over Goldberg et al. in view of Hayashi and Lefebvre. The examiner has also rejected claims 41-43 and 46 under 35 U.S.C. § 103(a) as being unpatentable over Hayashi in view of Abrams and Hayman et al. Finally, the examiner has also rejected claim 47 under 35 U.S.C. § 103(a) as being unpatentable over Hayashi in view of Lefebvre. Applicants respectfully traverse these rejections.

All of the rejections under 35 U.S.C. § 103 are based principally upon either Cathcart et al., Goldberg et al. or Hayashi. As explained above, none of these three references are directed to the problem of how to specifically locate a sensing device within the passageway of a mammalian patient. Accordingly, none of these three primary references discloses or fairly suggests, in any way, a method of anchoring a catheter having an inner lumen through which a sensing device can be transported, i.e., an inner lumen having a bore which extends "completely through the inner lumen from the proximal end to the

distal end." Moreover, nothing in any of the secondary references discloses or suggests this very important feature of the invention.

Accordingly, since no combination of any of the references cited in this application disclose or fairly suggest the use of an inner lumen having a bore extending from its distal end to its proximal end, there is no basis for deeming obvious any of the claims in this application. No individual of ordinary skill in the art, having knowledge of the references cited in the application, would have found it obvious to provide the unique anchoring system of the invention, including the use of an inner lumen having a bore extending completely through the inner lumen from the proximal end to the distal end. Accordingly, all rejections under 35 U.S.C. § 103 should be withdrawn and no additional rejections of other claims based upon 35 U.S.C. § 103 should be applied.

CONCLUSION

For the reasons set forth above, applicant respectfully submits that all of the claims remaining in the application are

now in condition for allowance. Accordingly, reconsideration, reexamination and allowance of all claims is requested.

Respectfully submitted,

SHELDON & MAK

Dated: March 26, 2001

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on March 26, 2001.

Signed: March 26, 2001 By: _____
Jennifer Ankai
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